Overview of Research, and the Human Research Protection Framework

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What is Research?

- Research seeks to gain knowledge. It may be defined as a systematic investigation or study to establish facts and provide new knowledge.

- Research with human beings include any social science, biomedical or epidemiological activity that involves a systematic collection or analysis of data – which has the intent of generating new knowledge.
What is Research?

- We here are concerned with research that involves human beings who are exposed to observation, intervention, manipulation, or other interaction with investigators.

- This interaction may occur directly, or through an alteration of the environment, or persons may become individually identifiable through the investigator’s collection, preparation, or use of biological material or the use of medical or other records.
What is Research?

- Research may also be done to confirm or verify previous findings in order to establish facts or bring greater clarity to a subject area.

- So – the criteria for research involves two (2) features:
  a. Data collection to be used for new knowledge, which is generalizable
  b. Human beings or their data that are ‘used’ in the process

- Issues such as whether individuals may be personally identifiable help to determine their relative risk of harm.
Proper research processes have three (3) essential components...
The Research Process:

- Proper design of the Research
- Proper conduct of the research
- Research Ethics
What is Research ethics?

• The field of Research Ethics is devoted to the systematic analysis of the research process, to ensure that participants in a study are protected, and that research involving human subjects is conducted in a way that serves the needs of participants as well as those of society.
Rationale for Research Ethics:

• Health research in the Caribbean is vital and imperative to continuously improve the health and well-being of our citizens, but concomitant with such research should be all efforts to safeguard the welfare of the research participants.

• To ensure the latter, RECs/IRBs here and around the world have the responsibility to ensure that all the ethical requirements for research with human participants are met by all researchers.
Research Ethics:

**Internationally:**
- Different regulatory frameworks
- Greater need to coordinate
- Problem in ensuring standards across varying locations
- Different needs to address, in terms of health, etc.
- Trying to figure out – What is ethically correct in each case?

**Regionally:**
Research Ethics is challenging!
- Perception that research is inherently unethical
- Insufficient research ethics training
- Overworked REC/IRBs with no resources (practical difficulties for ethics review, diminished legitimacy)
- Lacking normative regulatory frameworks for human subjects research (to deter unethical research and compensate where harm occurs)
- Depends solely on individual investigators to carry through on their promise!
Research Ethics:

We therefore need Good Research Ethics Systems in our Region!

- Efficient, rigorous & transparent RECs/IRBs
- Appropriate normative & regulatory framework
- RECs/IRBs and Investigators trained in Research Ethics
- Effective Oversight of Research – including the RCR – the Responsible Conduct of Research
- The proper registration of Clinical Trials
- Mechanisms for support (i.e. Consulting services), e.g. CARPHA’s REC, CANREC (The Caribbean Network of Research Ethics Committees)
THE HUMAN RESEARCH PROTECTION FRAMEWORK

[Three (3) Elements]
The Protection Framework:

- The Human Research Protection Framework
- The Responsible Conduct of Research
- Research Ethics Review
- Research Regulation
The Human Research Protection Framework:

- **RESEARCH** - The Research Proposal (Properly designed)

- **RESEARCH ETHICS REVIEW** – The *a priori* review of research proposals that prevent unethical research from proceeding

- **RCR** – The Responsible Conduct of Research ( Properly executed)

- **REGULATION** – The Legal safeguards and provisions to regulate Research (To deter unethical research and to compensate)
Critique of our system in the Caribbean:

- We are trying to make one ELEMENT of the System do the work of the other Elements in the System, or for the ENTIRE system! (i.e. Research, RCR, Research Ethics Review, and Regulation)

- No one element can possibly do ALL tasks! For example:
  - Regulation (Law) cannot replace Ethics Review
  - Research Ethics training cannot replace Regulation
  - Ethics Review cannot replace mechanisms for RCR – the Responsible Conduct of Research
Critique of our system in the Caribbean:

- So whilst effective oversight by an efficient and rigorous REC/IRB is good (which includes the responsible conduct of research), you also need the proper registration of research and regulation, as well as appropriate on-going research ethics training – as we are now having.
Rationale: Regulation to Protect Research Participants

• The legal regulation of research as well as research ethics are important because the human subjects of research may be harmed.

• Further, not all risks can be predicted in advance, hence laws should be written to ensure compensation for research harms.
Our current state:

- Some Caribbean countries are presently being approached for conducting drug studies and similar research, perhaps because they are viewed as not having the very stringent ethical and legal requirements for research that exists in the more developed countries.
The International Compilation of Human Research Standards:

- This compilation enumerates over 1,000 laws, regulations, and guidelines that govern human subjects research in 113 countries. [http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html](http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html)

- It was developed by the Office of Human Research Protections (OHRP) in the USA, and is updated yearly - for use by researchers, IRBs/RECs, and sponsors of research.

- This listing is freely available on the web and tells at a glance which countries have laws, regulations, and guidelines for human research and which do not!
Regulation to Protect Research Participants

• CARPHA’s Position Paper draws attention to the need by CARICOM Ministers of Health to now regulate the conduct of research with human participants, in order to provide best practices, ensure consistency and harmonization, and protect the countries in the region from harmful exploitative research activities through legislation, as a matter of urgency.
Our Research Ethics system in the Caribbean:

- All ELEMENTS of the Research Ethics System are necessary:
  - To ensure that research is ethical, and to develop trust in research as an ‘institution’
  - Ethics should not be confused with ‘Compliance’. Compliance (enforced by law) is important, but ‘ethics’ should not be reduced to mere compliance. Ethical deliberation and analysis of specific proposals – can’t be ‘dictated’ beforehand by any legal document! There is no ‘algorithm’ to address all the issues in a research proposal!
  - Research quality is also important in every proposal!
Our Tasks:

1. We therefore need to support all ‘Elements’ of Research Ethics Systems, while advancing a systemic view.

   Note: ‘Ethics review’ is an irreplaceable piece of the Research Ethics System

2. We need to address practical issues:
   a) Processes that impact our capacity to protect research participants
   b) Adopt a more practical approach to training.

   Research ethics training should exist at all levels!
A Systemic approach to Research Ethics:

**Hence the Important Steps:**

- The submission of properly designed research proposals
- The conducting of ethical review
- The Monitoring of approved protocols
Conclusion:

• Research is important to establish facts and provide new knowledge.
• Conducting research has three important aspects:-
  ➢ Practical (empiric) aspects
  ➢ RCR (Responsible Conduct)
  ➢ Research Ethics
• Ensuring research ethics standards internationally and regionally is challenging!
Conclusion:

- However, effective oversight by an efficient and rigorous REC/IRB is crucial for the well-being of research participants.

- We should also be totally conversant with, and fully support all Elements of Research Ethics Systems!